Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

****

HON ROBERT B. KUGLER

THIS DOCUMENT APPLIES TO ALL CASES

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Remote Videotaped Deposition of DAVID L. CHESNEY, commencing at 9:40 a.m., on the 21st of March, 2022, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked Highly Confidential
PAGE LINE
None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now recording and on the record. My name is David Stone. I'm a legal video specialist on behalf of Golkow Litigation Services.

Today's date is March 21st, and the time is 9:40 a.m.

This is the deposition of David Chesney in the matter of In Re: Valsartan, Losartan, and Irbesartan Products Liability Litigation, plaintiffs, versus -- in the United States District Court, District of New Jersey, Case Number, MDL Number 2875.

This deposition is being taken via remote recording on behalf of the plaintiffs.

The court reporter is Maureen Pollard.

Counsel will state their appearances, and the court reporter will administer the oath.

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this quality problem, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. And you've actually written on that subject and published on that subject, correct?
A. Yes.
Q. You would agree with me as a matter of GMP that the information in this e-mail could not be ignored; it needed to be aggressively evaluated by the so-called, quote-unquote, leaders as soon as it was brought to their attention, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. And we know in retrospect that what Dr. Lin said about the valsartan quenching creating the NDMA and this being a common problem in the production and synthesis of sartan APIs, we know in retrospect he was 100 percent correct about those statements. You've seen that in the

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materials you've reviewed for this case, right?
MR. FOX: Objection to form. Argumentative.
A. Ultimately that information was developed, yes.
BY MR. SLATER:
Q. Are you stunned to see this e-mail, and to see that this information was being circulated within ZHP as of July 2017? Because you said it's the first time you've become aware of that.
MR. FOX: Objection to form.
BY MR. SLATER:
Q. Are you stunned, shocked, surprised? What word would you put on it?
A. I wouldn't say stunned. It sounds to me like an appropriate notification based on some information that is outlined in the e-mail.
It's a few months before -- actually about -- let's see here, about 10 or 11 months before the recall, and these things are -- complex scientific issues like this

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don't get resolved overnight.
I don't know what was done about this, whether this was a triggering point for further work that culminated in the notification to FDA and the recall, or what.
But it certainly is responsible for Dr. Lin to have made this notification, and it looks like he made it to the right people.
Q. We know, again in retrospect, that what Dr. Lin said is accurate, and we know that he must have had a way to know it because -- well, rephrase.
You're certainly not taking the position that he just came up with this out [redacted]
MR. FOX: Objection.
MR. SLATER: Chris, let's go to

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the article in the Quality Management Essentials publication that I just mentioned a moment ago indirectly, please.
And I'm not sure what exhibit number would this be for the record, if anybody knows.
MR. GEDDIS: That would be Exhibit 5.
(Whereupon, Chesney Exhibit Number 11 was marked for identification.)
MR. FOX: Which exhibit is this on the screen?
MR. SLATER: I think I was just told Exhibit 5.
MR. FOX: So this has not been used before.
MR. SLATER: This has not been used before.
BY MR. SLATER:
Q. And you recognize this publication, Quality Management Essentials, Expert Advice on Building a Compliant System?

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You recognize this publication from 2018, correct?
A. I don't recognize the artwork, but I recognize the title, yes.
Q. And if we go to the third page, the Table of Contents, we can see that you actually wrote an article that was included in this publication titled Executive Responsibility for Quality, correct?
A. Yes, that's correct.
Q. Let's go to your article which comes right after that. And this is titled -- rephrase.
Your article is titled Executive Responsibility for Quality, and I want to go to the section titled Importance of Quality just below that.
MR. SLATER: Chris, could you make it a little bigger, please?
Perfect.
A. That's fine.
Q. This says, "Importance of Quality.
"Executive commitment to

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quality in the pharmaceutical industry is critical, not only to ensure continuing profitability of the company, but also for the safety and well-being of patients and to meet the needs of healthcare providers who prescribe and use pharmaceutical products every day."
That's what you wrote, correct?
A. Yes.
Q. The primary concern has to always be the safety and well-being of patients, right?
A. Yes.
Q. It would never be acceptable for ZHP or any other company to place profits over safety, right?
MR. FOX: Objection to form.
A. I agree with that.
BY MR. SLATER:
Q. For example, if it turned out that ZHP was making so much money with the zinc chloride process to manufacture valsartan API that they chose to keep secret from its customers and the regulatory

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authorities that they knew there was NDMA in the valsartan because they were so enamored with the profits they were making and put that ahead of the safety of people using those pills, that would be reprehensible, right?
MR. FOX: Objection to the form. Argumentative, no foundation, beyond the scope of his expertise.
A. It would be of great concern, yes.
BY MR. SLATER:
Q. It would be reprehensible, right?
MR. FOX: Objection. Same objection.
A. That's a value judgment word. I prefer more precise terminology. But it would not be a good thing.
BY MR. SLATER:
Q. Going down a little further to the fourth full paragraph under Importance of Quality, there's a paragraph that says, "For these reasons, quality assurance (QA) and GMP

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compliance may be viewed differently in the pharmaceutical industry than in those industries where a reputation for high quality drives sales. Quality assurance may be viewed as a 'cost of doing business' or an internal 'police department' issuing directives that delay or prevent product release. That viewpoint can result in a low priority being assigned to quality operations and resourcing, which can lead in turn to quality problems, regulatory difficulties, unnecessary expense, adverse publicity, lawsuits and investor disappointment. All these consequences are preventable if executive managers understand the importance of the quality assurance function and treat it as a critical business operation just like other critical areas, such as strategic planning, financial management and others."
That's what you wrote because you believed it to be true, correct?
A. Yes, sir.
Q. Let's go now to the next page. There's a heading that says Regulatory

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Considerations. And you wrote, "In addition to the business benefits, health regulatory agencies around the world both require and expect top management to support a strong quality assurance function for their companies."

Top management would include, for example, the chairman of ZHP, Mr. Baohua Chen; he would fall within the context of top management, right?

A. Yes.

MR. FOX: Objection.

I'm sorry, Adam, I didn't hear the name that you mentioned.

MR. SLATER: I said Baohua Chen. Mr. Baohua Chen.

BY MR. SLATER:

Q. You then go through, after introducing this section, a couple of cases from the US Supreme Court that addressed the executive responsibility for certain regulatory violations, correct?

A. Yes.

Q. The first case you talk about

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is US versus Dotterweich where you say that "Mr. Dotterweich's company, Buffalo Pharmacal, was inspected by the FDA, resulting in direct adulteration and misbranding findings. The FDA criminally prosecuted Mr. Dotterweich and the company, charging that as president, he was ultimately responsible for the company's actions and therefore should be found guilty of violating the law."

And you put that in the article because you found that to be a significant case and a significant cautionary tale, correct?

A. Yes.

Q. You said, "Following a District Court case and subsequent appeal, the Supreme Court ruled on his case and concluded that as president, he could be held responsible for the acts of the corporation even though he did not know of the violations and did not intend for them to occur. This has become known in the US as the Doctrine of Strict Liability, or 'Responsible Corporate Officer'

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doctrine. It applies to those who, in the words of the Court, '...stand in a responsible relationship to the acts of the corporation.'"

And again, you stated this because you're cautioning the executives in pharmaceutical companies to take their quality obligations very seriously, right?

A. Yes.

Q. You then talk about the Park case, US v. Park, and you say in part, "Like Mr. Dotterweich, Mr. Park defended himself by claiming that he was not involved in the conduct that violated the law and that he had delegated authority to 'dependable subordinates' he trusted to do the right thing."

And a little further down you actually quote from the majority opinion from the Supreme Court stating, "The Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will ensure that violations will not

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occur.

"The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding and even onerous, but they are no more stringent than the public has the right to expect. We are satisfied that the Act imposes the highest standard of care and permits conviction of responsible corporate officials, who in light of this standard of care, have the power to prevent or correct violations."

And you quoted that language because you felt it to be, again, not only a cautionary tale, but right on point to get the attention of executives, correct?

A. That's right.

Q. When you talk about demanding and even onerous obligations and the highest standard of care, those statements would apply to ZHP, too, right, and their executives, correct?

MR. FOX: Objection to form. Calls for conclusion.

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A. In my opinion they apply to anyone in the FDA-regulated industries.
BY MR. SLATER:
Q. Looking now on page 5, if you could. Towards the bottom, you provide at the bottom, you say, "some general suggestions that apply to all companies in this industry, regardless of size or complexity."
And number 1, you say, "Executive managers must recognize the criticality of a strong quality assurance organization and quality system to patient safety and to the company's business success."
And that's an important foundational point, right, that QA has to be prioritized? Right?
A. Yes.
Q. Looking at number 2, "Quality management must be seen as similar to other critical business management activities executives participate in, such as strategic planning, budget management, succession

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planning and other areas."
And then number 3, you say, "Executive management teams must support their QA organization with authority and resources that are equal to the responsibility they have."
And then you say a little further down that the structures within the company "must assure that the quality unit can make decisions without undue influence from other organizational components and avoid conflict of interest."
Again, these are all what you believe to be very important points for any responsible company to follow, correct?
A. Yes, that's correct.
Q. Number 4, you wrote, "Executive management must establish a strong quality policy that makes it clear the company is committed to consistently producing high-quality products that perform clinically as intended. Day-to-day statements and actions of top level executives must demonstrate that this commitment is real, not

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just words on paper."
I wanted to ask you about the "words on paper" part, because that jumped out to me when I read this.
That's an important point to you, that it's not enough just to put these policies in writing, but you actually have to be committed to following through with them and taking these obligations seriously, right?
MR. FOX: Objection to form.
A. Yes.
BY MR. SLATER:
Q. Number 5, you say, "As with other management responsibilities, executive teams must be kept aware of the performance of the quality system and of any emerging problems that are being dealt with."
MR. FOX: Is that a question?
BY MR. SLATER:
Q. That's another important point that you felt needed to be communicated to executive management in pharmaceutical companies, correct?

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A. Yes.
Q. And I think overall what I'm hearing here is that the top level management has to essentially make very clear to everyone in the company that quality is very important, safety is very important, and it should never be minimized and never be put aside for considerations of profit, correct?
MR. FOX: Objection to form.
A. Yes, correct.
BY MR. SLATER:
Q. Did you read in the FDA documents where Jung Du told the FDA investigator that the zinc chloride process allowed them to increase their yield and lower their cost, and to thus dominate the world market for valsartan?
Did you see that statement?
A. Yes, I did.
Q. That's a concerning statement to you, isn't it?
MR. FOX: Objection to form. Calls for speculation.
A. Well, it's a statement that's

not unreasonable to make if there are benefits to -- you know, enhancing the process for those reasons, that's fine, as long as these other principles we've been discussing are given proper consideration. There's nothing wrong with improving a process, there's nothing wrong with being profitable for that matter, provided that these other principles are respected.

BY MR. SLATER:

Q. With regard to the e-mail I showed you from July of 2017, matched up against what Jung Du told the FDA investigator, does that cause you some concern about whether or not ZHP kept secret its knowledge that there was NDMA in their valsartan because they were making so much money?

MR. FOX: Objection. Calls for speculation.

A. I don't see any connection on the surface of it. I think that e-mail by itself certainly is the type of upward communication that I'm talking about here

that should be made on a regular basis. But there are many questions about what was then done about it, how complete and accurate its foundation was and all that.

But that's exactly the sort of thing that should be -- questions that should be asked when someone like Dr. Lin raises that kind of an issue to upper management.

BY MR. SLATER:

Q. If a decision was made not to investigate in any detail this issue and not to disclose it in any reports or to anybody because of the profits that were being made with this valsartan API, that would be a very, very serious problem, right?

MR. FOX: Objection to form. Calls for speculation, argumentative.

A. I've certainly seen no evidence that that was the case. But if it was the case, then yes, it would be of concern.

BY MR. SLATER:

Q. Going now to the Summary at the -- one second actually.

Looking at the next section, it

says, "Common Mistakes Executive Teams Make," number 3 you wrote, "Emphasizing production quotas and market demands to the extent that quality problems are overlooked or regarded as unimportant - worst case, deliberate coverup of known quality problems through falsification of records." I'm going to stop there.

When you say, "worst case, deliberate coverup of known quality problems through falsification of records," you're saying that would be as bad as it gets pretty much, right?

A. Yes.

Q. Are you aware that -- well, rephrase.

To the extent that ZHP knew there was NDMA in its valsartan as of July 2017 or earlier, yet continued to represent to customers and regulators and the world that what they were selling was valsartan of the expected quality and the expected purity and didn't disclose the NDMA deliberately, that would be as bad as it gets, right?

MR. FOX: Objection to form.

BY MR. SLATER:

Q. If that happened, that's as bad as it gets, right?

MR. FOX: Objection to form. Lacks foundation, calls for speculation.

A. I don't see enough in the July 2017 e-mail to enable me to conclude with finality that the premise of your question is accurate.

There certainly are some concerns expressed there that are appropriate to express, they're being expressed to the right people. But full background and all the facts would have to be delved into with considerable effort in order to reach a conclusion that would have that much impact.

BY MR. SLATER:

Q. If the conclusion that I postulated were the facts, you would agree that that would be about as bad as it gets, right?

MR. FOX: Objection to the

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form. Calls for -- it's argumentative.

A. Once again, if after a complete investigation considered all the facts, if it was established and proven based on objective evidence that information existed that was known was deliberately covered up or anything was falsified, then that would be a very serious violation, yes.

BY MR. SLATER:

Q. Looking now at the Summary, you talked about the fact that there is a "growing consensus about the most critical quality management concepts." And you say, "First among those is that executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health."

And you would apply those -- that point to ZHP? Those points would apply to ZHP, right?

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A. I'm sorry, Adam, can you just have that repeated? It got garbled.

Q. This would apply to ZHP, correct?

MR. FOX: I'll object to the form because I didn't hear it.

BY MR. SLATER:

Q. I read the -- I'll do it again.

You say in the Summary that certain -- rephrase.

You say in the Summary that there's a "growing consensus about the most critical quality management concepts. First among those is that executive management teams are the key to a company's ability to successfully meet quality standards on a consistent basis. Doing so is critical to proper clinical performance of the products of this industry and therefore, ultimately, to global public health."

And you would agree that within ZHP, the ultimate responsibility lies with the executive management team, correct?

MR. FOX: Objection to form.

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A. Yes, I would agree it applies to ZHP and everybody else in the industry.

BY MR. SLATER:

Q. Let's go to the last page, please. It's there already, sorry.

The last paragraph of this article says, "Prudent management teams recognize this and support their quality units both philosophically and materially, with strong policies backed up by consistent actions, authority and resources. Failure to do so may have both serious business consequences for the company and potentially even personal consequences for individual executives."

Again, that's a statement that you believe would hold true for ZHP and any company in this industry, right?

A. Yes, any company in this industry.

Q. Going back to the events of 2017, if ZHP knew that there was NDMA in its valsartan as of at least July 2017, yet continued to manufacture that valsartan with

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the zinc chloride process, didn't change anything, didn't tell anybody, every pill manufactured with that process would be adulterated, right?

MR. FOX: Objection to form.

A. I'm sorry, I'm giving some thought to the way you phrased that, not the concept, but just the phraseology.

If there was proven evidence that the process was contributing NDMA at harmful levels, and they allowed that to continue and continued to sell the product, and particularly if there was any deliberate effort to conceal that, then yes, that would be very serious.

MR. SLATER: If you guys need a break, this would be a good point because I'm going to shift to something else. But if you don't need a break, I can do it.

MR. FOX: Let's take a break, Adam, because I have to take care of something else for a few minutes, too.

A. I need a couple minutes.

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How much time do you want to take here?
MR. FOX: About 3:15?
THE WITNESS: Okay. What time is it now?
MR. SLATER: That's fine.
THE WITNESS: Okay. 3:15 is good.
MR. SLATER: Thank you.
THE VIDEOGRAPHER: The time is 2:54 p.m. We are off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time is 3:23 p.m. We are back on the record.
BY MR. SLATER:
Q. Mr. Chesney, have you seen any indication in anything you've seen that ZHP has ever notified the FDA about the contents of the July 2017 e-mail we discussed earlier?
MR. FOX: Objection to form.
A. The existence of the e-mail itself?
///

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BY MR. SLATER:
Q. Well, the contents we've been talking about, including that there was NDMA in valsartan --
A. Well, the --
Q. -- how it was being created at the quenching of the sodium azide, the sodium nitrite, and that it was a common problem with sartan APIs?
MR. FOX: Objection to form. Argumentative, lacks foundation.
A. There was extensive back and forth with the FDA. ZHP submitted a tremendous amount of scientific data. FDA asked questions, ZHP responded. I've seen a lot of that. Some of it may have contained information that was foundational to that July of '17 e-mail or may not.
But the existence of the e-mail itself, I haven't seen reference. It's just the information that it refers to may have been wrapped up and included in some other discussions that were held with the FDA.
///

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BY MR. SLATER:
Q. I understand you're saying maybe it was, but nothing you can recall seeing as you sit here now, right?
A. No, and nothing specific about that particular e-mail.
Q. Did you see any indication in anything you reviewed where ZHP suggested to the FDA or anybody else that it was known internally that there was NDMA in valsartan, and that this was caused by the quenching of the sodium azide with the sodium nitrite, that that was known before June of 2018? Have you seen anything indicating they ever told that to anybody?
MR. FOX: Objection to form. Lacks foundation, argumentative.
A. Again, I would have to look at the correspondence back and forth to refresh my memory as to what happened when and what they told the FDA about the timeline. But as I sit here, I can't recall anything.
BY MR. SLATER:
Q. I'm going to jump through a

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couple of things with you.
One of the things I noticed in your report was that you said that the time period that you focused on was August 2013 to October 2019, other than, I think, one complaint from 2010 that you found on the FDA website.
Do I understand that correctly?
A. Not exactly. That wasn't a complaint on the FDA website. It was a record of a prior inspection. And there was -- you know, that was not within that bracketed time period.
But the majority of the documents I reviewed were within that bracketed time period.
Q. Do you have any understanding -- rephrase.
Why would the time period you were looking at beginning 2013 when the manufacturing process change was vetted and evaluated in 2011?
A. Well, the primary remit I was given was to opine on what the record showed